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Date: May 29, 2003	Client & Matter Number : 15270J-004762US	No. Pages (including this one): 13
To: Examiner Sharon Turner USPTO	At Fax Number: (703) 746-3141	Confirmation Phone Number: (703) 308-0056
From : Romy L. Celli		(5465)
<p>Message: 09/724,552</p> <p>Examiner Turner:</p> <p>Please find the following papers filed with the USPTO on March 24, 2003:</p> <ol style="list-style-type: none"> 1. Transmittal Form (PTO/SB/21) (1 page); 2. Response to Restriction Requirement and Additional Restriction Requirement (8 pages); 3. Petition for Extension of Time (PTO/SB/22) (1 page, submitted in duplicate); 4. Return Receipt Postcard. <p>Please do not hesitate to contact me regarding this or any other matter on our mutual dockets.</p> <p><i>Romy Celli</i></p>		
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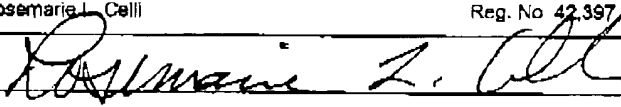
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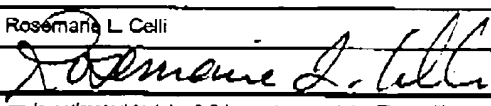
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TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	09/723,544	
	Filing Date	November 28, 2000	
	First Named Inventor	Schenk, Dale B.	
	Group Art Unit	1647	
	Examiner Name	Turner, Sharon	
Total Number of Pages in This Submission	12	Attorney Docket Number	15270J-004762US

ENCLOSURES (check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input checked="" type="checkbox"/> Response to Restriction Requirement & Additional Restriction Requirement (8 pp) <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input checked="" type="checkbox"/> Extension of Time Request (1 p., submitted in duplicate) <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s)	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Return Receipt Postcard
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Firm and Individual name	Townsend and Townsend and Crew LLP Rosemarie L. Celli Reg. No. 42,397	
Signature		
Date	March 24, 2003	

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Typed or printed name	Rosemarie L. Celli	
Signature		Date March 24, 2003

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UNITED STATES PATENT AND TRADEMARK OFFICE

Mailing Date: March 24, 2003
Application of: Dale B. Schenk *et al.*
Application No.: 09/723,544

Via First Class Mail

Filed: November 28, 2000

Please stamp the date of receipt of the enclosed documents and return this card to addressee:

1. Transmittal Form (PTO/SB/21) (1 page);
2. Response to Restriction Requirement and Additional Restriction Requirement (8 pages);
3. Petition for Extension of Time (PTO/SB/22) (1 page, submitted in duplicate);
4. Return Receipt Postcard.

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PATENT
Attorney Docket No.: 15270J-004762US
Client Ref. No.: 209-US-CIP8BC2

TOWNSEND and TOWNSEND and CREW LLP

By: Rosemarie L. Celli

Rosemarie L. Celli

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

DALE B. SCHENK et al.

Application No.: 09/723,544

Filed: November 28, 2000

For: PREVENTION AND TREATMENT
OF AMYLOIDOGENIC DISEASE

Examiner: Turner, Sharon

Art Unit: 1647

RESPONSE TO RESTRICTION &
ADDITIONAL RESTRICTION REQUIREMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

This paper is submitted in response to the Office Action mailed September 23, 2002. A petition to extend the time of response from October 23, 2002 to March 23, 2003 is submitted herewith. This paper is timely submitted on March 24, 2003 as March 23, 2003 fell on a Sunday.

I. Restriction Required Under 35 U.S.C. § 121

Applicants elect Group I, claims 69-78, with traverse. It is applicants' position that the restriction requirement is improper because the same claims are restricted into more than one Group

A. Groups I and II

The Examiner is requested to consider rejoining Group I with Group II for prosecution in the same application. Group I consists of claims 69-78; and, Group II consists of

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claims 69-78. The result of the restriction is that claims 69-78 have been restricted into two groups, i.e., Group I and Group II. Election of Group I and prosecution of claims 69-78 in one application and election of Group II and prosecution of claims 69-78 in different application might result in claims 69-78 issuing in two separate patents for the same invention.

B. Groups III and IV

The Examiner is requested to consider rejoining Group III with Group IV for prosecution in the same application. Group III consists of claims 82-92; and, Group IV consists of claims 82-92. The result of the restriction is that claims 82-92 have been restricted into two groups, i.e., Group III and Group IV. Election of Group III and prosecution of claims 82-92 in one application and election of Group IV and prosecution of claims 82-92 in different application might result in claims 82-92 issuing in two separate patents for the same invention.

C. Restriction to Groups I and II, and Groups III and IV is Improper

Under 35 U.S.C. § 121, an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent or distinct. "IT STILL REMAINS IMPORTANT FROM THE STANDPOINT OF THE PUBLIC INTEREST THAT NO REQUIREMENTS BE MADE WHICH MIGHT RESULT IN THE ISSUANCE OF TWO PATENTS FOR THE SAME INVENTION." (See MPEP § 803.01, emphasis found in the original.) It is respectfully submitted that it is self-evident and incontrovertible that the restriction of claims 69-78 into Groups I and II and the restriction of claims 72-82 into Groups III and IV are both improper.

II. Additional Restriction Requirement

The Examiner has required further restriction of the elected claims on two grounds: (1) the claims have been presented in an improper Markush form (see p. 2 of the restriction requirement); and, (2) further restriction is required under 35 U.S.C. § 121 (see p. 5, of the restriction requirement). Applicants respectfully point out that, "The 'unity of invention'

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concept is not to be confused with the 'misjoinder concept under 35 USC 121' rejection employed in *In re Weber*. See *In re Harnish*, 206 USPQ 300 (CCPA 1980).

In response to the additional restriction requirement, Applicants make the following elections with traverse:

1. An internal cleavage product F) A β 1-3;
2. A T helper cell epitope B) diphtheria toxoid; and,
3. N which is the first B) 3 amino acid residues.

Election of Group I, claims 69-78, renders an additional election for remaining Groups moot.

A. Additional Restriction Required on the Grounds that the Claims are Allegedly Presented in Improper Markush Format

Applicants acknowledge the Examiner's comment that "applicants have presented instant claims in an improper Markush format." It is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. See *In re Harnish*, 206 USPQ 300 (CCPA 1980); *Ex parte Hozumi*, 2 USPQ2d 1059 (Bd. Pat. & Int. 1984); MPEP § 803.02. It is the Examiner's position that the claims are improperly set forth as they are genus claims which fail to share the characteristics of a genus, *i.e.*, a common utility and a substantial feature essential to the disclosed utility.

1. The Additional Restriction Requirement Can Only Apply to Claims Using Markush Style Claiming

Applicants respectfully point out that only claims 71, 75, and 76 recite a Markush group. The subject matter of claims 69-70 and 72-75, and 77-78 is not claimed using the Markush style of claiming. A Markush group recites members as being "selected from the group consisting of A, B, C, and D" or "wherein R is A, B, or D." See *Ex parte Markush*, 1925 C.D. 126 (Comm'r Pat. 125); MPEP § 2173.05(h). Thus, the Examiner's comments regarding improper Markush claims cannot apply to claims 69-70 and 72-75, and 77-78.

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2. The Subject Matter of Claims 71, 75, and 76 Possess Unity of Invention

The subject matter of claims 71, 75, and 76 possess unity of invention; and, therefore, should be examined. Claim 71 recites, "[an] internal peptide cleavage product has an amino acid sequence selected from the group consisting of A β 1-39, A β 1-40, A β 1-41, A β 1-42, and A β 1-43." The members of the Markush group recited in claim 71 have substantial structural similarity, and similar physical and chemical properties; each member shares at least 39 amino acids every other member. Each member of the group serves a similar function, *i.e.*, eliciting an immunogenic response to A β and thereby preventing or treating diseases associated with amyloid deposits of A β in the brain a patient. Thus, the Markush group of claim 71 is not misjoined because unity of invention exists for the compounds included within the Markush group.

Claim 75 recites "wherein said T helper cell epitope is derived from tetanus toxoid, diphtheria toxoid, hepatitis B surface antigen, Malaria CS, *E. coli* toxoid, or a toxoid from other pathogenic bacteria." Claim 76 recites the sequence identifier of the amino acid sequence encoding its respective T helper cell epitope. All members of the Markush group share a common utility, *i.e.*, they help elicit an immune response. They all share a substantial structural feature disclosed as being essential to the invention, *i.e.*, an epitope recognized by a T helper cell. Thus, the Markush group of claims 75 and 76 are not misjoined because unity of invention exists for the compounds included within both Markush groups.

B. Further Restriction is Allegedly Required Under 35 U.S.C. § 121

The Examiner states that further restriction is required under 35 § U.S.C. 121 to delineate the molecular embodiments to which the claims will be restricted in accordance with the elected group (*see* p. 4, first full paragraph of the restriction requirement) and because the inventions are distinct from each other (*see* p. 5, first full paragraph). It is applicants' position that § 121 does not provide a basis for rejection of a claim.

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As a preliminary matter, alleging that a particular claim represents multiple patentably distinct inventions is a *de facto* rejection of the patentability of the claim, because the claim cannot issue as drafted. As the C.C.P.A. noted:

As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the rights of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

See, In Re Weber, Soder and Boksay 198 USPQ 328, 331 (C.C.P.A. 1978). *See also, In Re Haas* 179 USPQ 623, 624, 625 (*In Re Haas I*) (C.C.P.A. 1973) and *In Re Haas* 198 USPQ 334-337 (*In Re Haas II*) (C.C.P.A. 1978).

Moreover, it has been held that an Examiner may not reject a particular claim on the basis that it represents independent and distinct inventions. *See, In Re Weber, Soder and Boksay, Supra*. The courts have ruled that the statute authorizing restriction practice, i.e., 35 U.S.C. § 121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. *See, In Re Weber, Soder and Boksay, In Re Haas I* and *In Re Haas II*. In the cases set forth above, the courts expressly ruled that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Patent Office to fashion such a rejection. As noted in *In Re Weber, Soder and Boksay*:

The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim-- no matter how broad, which means no matter how many independently patentable inventions may fall within it.

See, In Re Weber, Soder and Boksay at 334.

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Instead of imposing a restriction requirement on a single claim, the Office may limit initial examination to a reasonable number of species encompassed by the claim. *See*, 37 C.F.R. § 1.146. This practice strikes an appropriate balance between the concerns of the patent office regarding administrative concerns and unduly burdensome examination, and the clear constitutional and statutory rights of an inventor to claim an invention as it is contemplated, provided the dictates of 35 U.S.C. § 112 are complied with. *See*, the MPEP at 803.02. *See also*, *In Re Wolfrum* 179 USPQ 620 (C.C.P.A. 1973) and *In re Kuehl* 177 U.S.P.Q. 250 (C.C.P.A. 1973). Unlike a restriction requirement, a species election does not preclude an applicant from pursuing the original form of a claim in subsequent prosecution, nor does it force an applicant to file multiple divisional applications which are incapable of capturing the intended scope of the application.

In the present case, the practical distinction between a restriction and election of species requirement is a simple one. If the Examiner agrees that the claims are patentable, then claim 69 forms an allowable generic linking claim between the recited species, and the election of species requirement can be withdrawn as between these species (*see* MPEP 809.02(c)(B)(1)). It is believed that such would not impose a serious burden on the Examiner. By contrast, a restriction requirement would effectively require applicants to file a divisional application on claims whose patentability has already been established in the present case.

As a preliminary matter, alleging that a particular claim represents multiple patentably distinct inventions is a *de facto* rejection of the patentability of the claim, because the claim cannot issue as drafted. As the C.C.P.A. noted:

As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the rights of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not

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necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.

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Moreover, it has been held that an Examiner may not reject a particular claim on the basis that it represents independent and distinct inventions. *See, In Re Weber, Soder and Boksay, Supra*. The courts have ruled that the statute authorizing restriction practice, i.e., 35 U.S.C. § 121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. *See, In Re Weber, Soder and Boksay, In Re Haas I* and *In Re Haas II*. In the cases set forth above, the courts expressly ruled that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Patent Office to fashion such a rejection. As noted in *In Re Weber, Soder and Boksay*:

The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim-- no matter how broad, which means no matter how many independently patentable inventions may fall within it.

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Instead of imposing a restriction requirement on a single claim, the Office may limit initial examination to a reasonable number of species encompassed by the claim. *See, 37 C.F.R. § 1.146*. This practice strikes an appropriate balance between the concerns of the patent office regarding administrative concerns and unduly burdensome examination, and the clear constitutional and statutory rights of an inventor to claim an invention as it is contemplated, provided the dictates of 35 U.S.C. § 112 are complied with. *See, the MPEP at 803.02. See also, In Re Wolfrum* 179 USPQ 620 (C.C.P.A. 1973) and *In re Kuehl* 177 U.S.P.Q. 250 (C.C.P.A. 1973). Unlike a restriction requirement, a species election does not preclude an applicant from pursuing the original form of a claim in subsequent prosecution, nor does it force an applicant to

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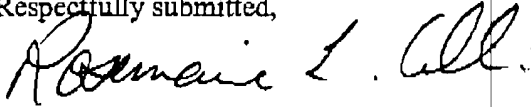
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file multiple divisional applications which are incapable of capturing the intended scope of the application.

In view of the foregoing, Applicants request Groups I and II, and Groups III and IV be joined; and, the additional restriction requirement be withdrawn with regard to the pending claims, claims 69-78, or alternatively be withdrawn with regard to claims 69-70, 72-74, and 76-78.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,


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